nqa usa
4 Post Office Square Road
Acton, MA 01720
United States
www.nqa-usa.com

COMPANY NAME: NASA Marshall Space Flight Center
REPORT NUMBER: AS-S08
AUDIT DATE(s): November14 - 17, 2006

MAIN SITE ADDRESS	OTHER SITES VISITED
Marshall Space Flight Center, AL 35812	

SCOPE OF REGISTRATION

ISO 9001:2000: All Products and Services Provided by the Marshall Space Flight Center. MSFC Supports the NASA Agency Infrastructure and is a Major Contributor to All Its Scientific and Technical Enterprises.
AS9100: Design, Development, Production, Installation and Servicing of Flight Hardware, Flight Software, and associated Ground Support Equipment Interfacing with Flight Hardware and Fight Software.

STANDARD APPLIED		ACTIVITY CATEGORY			
	ISO 9001		DOC REVIEW	X	SURVEILLANCE
X	ISO 9001 w AS9100		PRE-ASSESSMENT		REASSESSMENT
			ASSESSMENT		SPECIAL VISIT
					TRANSFER OF REGISTRATION

TEAM LEAD or LEAD AUDITOR	OTHER TEAM MEMBERS
Rick Giguere, ANAB # A03158, AIEA	

ACTIVITY CONCLUSIONS: (check all that apply)

- [X] CONFORMING — [4] NUMBER of MINORS RAISED
- [1] NUMBER of OBSERVATIONS or OPPORTUNITIES FOR IMPROVEMENT IDENTIFIED
- [X] REGISTRATION RECOMMENDED / CONTINUED REGISTRATION RECOMMENDED
- [ ] CORRECTIVE ACTION SUBMITTAL REQUIRED — [ ] WORKING DAYS (from report date)
- [ ] ON-SITE REVIEW OF CORRECTIVE ACTION REQUIRED
- [ ] NONCONFORMING WITH MAJOR NONCONFORMANCES — [ ] NUMBER of MAJORS RAISED
- [ ] REGISTRATION NOT RECOMMENDED
- [ ] SPECIAL VISIT REQUIRED — [ ] DURATION (audit days required)

SPECIAL COMMENTS

Previously identified NC's have been satisfactorily addressed or rewritten herein. (See NC, item #2 only)
NC's from all RMO audits have been satisfactorily addressed here as well.

LEAD AUDITOR	COMPANY REPRESENTATIVE
Rick Giguere	Robin N. Henderson

- Signature on this report by the assessed Company Representative indicates that this report, and any nonconformities and observations noted within, has been reviewed and accepted.
- Any nonconformities or observations identified are the result of a limited sampling process.
- The Internal Audit system is deemed effective unless noted otherwise within this report.
- This report remains under established confidentiality agreements between NQA and the assessed organization.
- **Prior to the initial assessment, the organization must have performed a full system internal audit, followed by a documented management review. The quality management system must be understood throughout the organization.**

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AS9100 ASSESSMENT MATRIX AND PLANNER

AS9100 REQUIREMENTS	LEGEND X = Element Fully Assessed P = Partial Element Assessed E = Exclusions Taken * = Audit each Activity	MANAGEMENT ACTIVITIES	RESOURCE MANAGEMENT	PRODUCT REALIZATION PLANNING	PRODUCT REALIZATION	DESIGN & DEVELOPMENT	REASSESSMENT ACTIVITY
4.2.1	DOCUMENTATION GENERAL	X		P		P	X
4.2.2	QUALITY MANUAL*	X	X	X	X	X	X
4.2.3	CONTROL OF DOCUMENTS	P		P	P	P	X
4.2.4	CONTROL OF RECORDS	X		P	P	P	X
4.3	CONFIGURATION MANAGEMENT	X					X
5.1	MANAGEMENT COMMITMENT	X					X
5.2	CUSTOMER FOCUS	X		P		P	X
5.3	QUALITY POLICY	X					X
5.4.1	QUALITY OBJECTIVES*	X	X	X	X	X	X
5.4.2	QMS PLANNING	X					X
5.5.1	RESPONSIBILITY & AUTHORITY	X					X
5.5.2	MANAGEMENT REPRESENTATIVE	X	P	P	P	P	X
5.5.3	INTERNAL COMMUNICATION	X		P	P	P	X
5.6	MANAGEMENT REVIEW*	X	X	X	X	X	X
6.1	PROVISION OF RESOURCES	P	X				X
6.2.1	HUMAN RESOURCES GENERAL		X				X
6.2.2	COMPETENCE, AWARENESS & TRAINING		X	P		P	X
6.3	INFRASTRUCTURE		X	P	P		X
6.4	WORK ENVIRONMENT		X	P	P		X
7.1	PLANNING PRODUCT REALIZATION			X			X
7.2.1	DETERMINATION OF REQUIREMENTS			X			X
7.2.2	REVIEW OF PRODUCT REQUIREMENTS			X			X
7.2.3	CUSTOMER COMMUNICATION			X			X
7.3	DESIGN & DEVELOPMENT					X	X
7.4.1	PURCHASING PROCESS			X			X
7.4.2	PURCHASING INFORMATION			X			X
7.4.3	VERIFICATION OF PURCHASED PRODUCT			X	P		X
7.5.1	CONTROL OF PROVISION				X		X
7.5.2	VALIDATION OF PROCESSES				X		X
7.5.3	IDENTIFICATION & TRACEABILITY				X		X
7.5.4	CUSTOMER PROPERTY				X		X
7.5.5	PRESERVATION OF PRODUCT				X		X
7.6	MONITORING & MEASUREMENT DEVICES				X		X
8.1	MEASUREMENT, ANALYSIS & IMPROVEMENT	X					X
8.2.1	CUSTOMER SATISFACTION*	X	X	X	X	X	X
8.2.2	INTERNAL AUDIT*	X	X	X	X	X	X
8.2.3	PROCESS MONITORING/MEASUREMENT	X			P		X
8.2.4	PRODUCT MONITORING/MEASUREMENT	P			X		X
8.3	CONTROL NONCONFORMING PRODUCT	P		P	X		X
8.4	ANALYSIS OF DATA*	X	X	X	X	X	X
8.5.1	CONTINUAL IMPROVEMENT*	X	X	X	X	X	X
8.5.2	CORRECTIVE ACTION*	X	X	X	X	X	X
8.5.3	PREVENTIVE ACTION*	X	X	X	X	X	X
	USE OF MARKS*	X	X	X	X	X	X

CURRENT SECTIONS COVERED (SURVEILLANCE NUMBER)		AS-S07		AS-S08		AS-S08	
FUTURE SURVEILLANCE PLANNING	NEXT VISITS						AS-S09
	FOLLOWING YEAR	TBD					

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AUDIT ACTIVITY RECORD

Audit trail reviewed / Personnel interviewed / Documentation reviewed / Departments or Processes Audited Objective evidence sampled

Reference also AS9101B checklist for further details

(5.6, 5.4.1, 8.2.1, 8.5.1, 8.4)
Interviewed Business Planning and Integration Office. L. Newton, Center Management Council, CMC, representative, R. Gladwin And Integrated Management System Board representative D. Miller. Reviewed charters for each, per PMD 1150.1, MPD1000.1, and MPD 1280.1

8.2.2, 4.2.3, 4.2.4, 8.5.2
Internal audit as per MPR 1280.6, Interviewed Kerry Warner/QD40.

5.2, 7.1, 7.2
Interviewed F. Lowry of Business Development

5.2, 7.1, 7.2, 7.3
Interviewed C. Coker, LOCAD Program
Interviewed Jeff Apple, High Energy Replicated Optics Project, (HERO)

7.4, 6.2.2
Interviewed Kellie Craig of Procurement Office, Noncompetitive Procurements
Interviewed Tania Rasberry and R. Sizemore (HEI) Safety and Mission Assurance on Procurement Quality Requirements (ECLSS)
Interviewed J. Jackson, Procurement Office, UNITES Contract
Interviewed T. Foley Batts, T. Jerry Williams, Procurement Training

7.4.3, 8.5.2
Interviewed Receiving Inspection, S. Blair, S&MA
Interviewed W. Woods, Supplier Audits, evaluations and Corrective action

8.5.1, 8.5.2, 8.5.3, 4.2.4
Corrective Action and Preventive action. Interviewed R. Jones HEI

AREAS OF GOOD PERFORMANCE

Use of SAAM system for processing Space Act Agreements
Procurement Training process and commitment to competency
Level of competency of personnel

AREAS FOR IMPROVEMENT

Back up/designee for personnel whose output to processes are maintained in personal space, i.e. on PC or locked cabinet, so pertinent information can be accessed.

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NONCONFORMANCES AND OBSERVATIONS

NUM	REF	ISSUES RAISED	CLASS
1	4.2.3	REQUIREMENT STATED: MPR 1050.2, Space Act Agreements and Other Transactions ISSUE RAISED: MPR 1050.2 includes requirements that are no longer reflective of the current process in areas such as records responsibility and concurrence requirements. A draft document is in process to address needed changes. This observation is noted to ensure changes are implemented.	OBS
2a	8.2.3	REQUIREMENT STATED: MWI 5330.2, NASA Engineering & Quality Audit, states that "A preliminary report shall be given at the exit briefing with a final report 30 days after the briefing." Also: "the team chairperson shall sign final verification of completed corrective action along with the project manager." ISSUE RAISED: Final reports are provided once per year at Summit, and final verification of corrective action is signed by Marshall field office personnel. **NOTE: This CA could not be verified as procedure was modified but evidence of compliance to new process was lacking. See 2b below.**	NC
2b	8.2.3	REQUIREMENT STATED: continued from 2a above. MWI5330.2 Rev. C, states that a final report shall be generated within 60 days after the exit briefing and shall include, a) a narrative summary of the audit. ISSUE RAISED: A final report dated Oct. 11, 2006, does not clearly present narrative summary.	
3a	7.3	REQUIREMENT STATED: EI51-OWI-001, Hardware Design and Development Porcess ISSUE RAISED: EI51-OWI-001 includes requirements that are no longer reflective of the current process such as: a) customer requirements shall be documented in any hard copy format, b) a log shall be kept by the EI51 Project Lead Engineer, c) Branch Chief releases design package. In addition, see below	NC
3b		REQUIREMENT STATED: EI51-OWI-001, para. 4.4.3.2.5.1 states that For drawings that exist only electronically, the EI51 Project Lead shall obtain the required approvals. ISSUE RAISED: It is not clear how these approvals are obtained or evidenced. Sampled drawing for PN 030604100 Rev A. No approvals evident.	
4	7.4.1	REQUIREMENT STATED: MWI 5330.1, para. 6.4.2.1 states that The Outsourcing Lead shall annually evaluate supplier nonconformances received to ensure there was no evidence of adverse trends. ISSUE RAISED: There is lack of objective evidence that these annual reviews are conducted. It should be noted that the person responsible was not present during the audit and there was no one available to access this information, if it was present.	NC
5	8.5.2	REQUIREMENT STATED: As part of the corrective action process the organization shall determine cause, evaluate the need for action, implement actions needed and record results. ISSUE RAISED: A review of RCAR 246, which derived from QSDN 177 on the ECLSS program, revealed a lengthy and potentially significant noncompliance, initiated in August 2006. As of the time of this audit there was no response to the request, but there is a request for extension (unapproved as yet) to July 2007, with a rationale of lack of resources. Product is set to ship in May.	NC

ASSESSMENT REPORT	*Assessing company logo*

GENERAL ASSESSMENT INFORMATION

1 Organization & Work Address

Company Name: NASA, Marshall Space Flight Center	Tel Number: 256-544-0451 Fax Number: 256-544-4155
Subsidiary of:	e-mail: robin.henderson@msfc.nasa
Organization Identification:	CAGE code:
Assessed Site Address: Huntsville, AL 35812	Assessment Representative & Title: Robin Henderson, Associate Director Quality Manager Representative & Title: Robin Henderson, Associate Director
Main activities: Product Types or Codes:	

2 ISO Registration

[ ] ISO Registered	Registrar Name: NQA-USA
[x] ISO Standard / Revision ISO 9001:2000	Expiration Date (If applicable):
[x] Aerospace Standard / Revision AS9100B	May 27, 2007

3 Assessment Team

Lead Assessor Name: Rick Giguere	Other Assessor Team Members:
[x] Certified Auditor – Type & No. A03158	
[ ] Qualified Auditor	

4 Assessment Dates: November 14-17, 2006

5 Assessment Scope

[ ] Total facility assessed	[ ] Initial assessment	[ ] All 9100 elements assessed
[x] Partial facility assessed	[ ] Re-assessment	[x] Partial 9100 elements assessed
[ ] Other:		Elements not assessed:
[ ] Activity assessed:		

6 Assessment Disposition	**7 Scoring**
[ ] Conforming	Scoring result: 90
[x] Conforming with minor (mi) corrective action	
[ ] Non conforming with Major (MA) corrective action	

8 Assessment Approval

Assessing Company	Date	Lead Assessor Name	Signature
NQA-USA	11/17/06	Richard Giguere	Rick Giguere

Distribution Agreement

This Assessment Report is the property of the assessed Organization and the assessing Company. Distribution to other companies or individuals is authorized only after written agreement of the assessed Organization and of the assessing Company.

Rick Giguere 11/17/06

ASSESSMENT REPORT	*Assessing company logo*

ASSESSMENT CONCLUSIONS
General comments about the organization and the quality system of the assessed organization: 1. Good overall consistency of management system.
1. Use of SAAM system for processing Space Act Agreements 2. Procurement Training process and commitment to competency 3. Level of competency of personnel
Improvement Opportunities: **1.** Back up/designee for personnel whose output to processes are maintained in personal space, i.e. on PC or locked cabinet, so pertinent information can be accessed.

ASSESSMENT REPORT

Assessing company logo

ASSESSMENT RESULT SUMMARY

Organization : NASA, Marshall Space Flight Center

Elements* (AS9100 – Section 1)	Result				Observation / Corrective Action Request Number (MA/mi)
	S	Ma	mi	N/A	
4 - Quality Management System					
4.1 General requirements	S				
4.2 Documentation requirements	S				
4.3 Configuration Management	S				
5 - Management responsibility					
5.1 Management commitment	S				
5.2 Customer focus	S				
5.3 Quality policy	S				
5.4 Planning	S				
5.5 Responsibility, authority and communication	S				
5.6 Management review	S				
6 - Resource managements					
6.1 Provision of resources	S				
6.2 Human resources	S				
6.3 Infrastructure	S				
6.4 Work environment	S				
7 - Product realization					
7.1 Planning of product realization	S				
7.2 Customer-related processes	S				1 Observation
7.3 Design and development			1		
7.4 Purchasing			1		
7.5 Production and service provision	S				
7.6 Control of monitoring and measuring devices	S				
8 - Measurement, analysis and improvement					
8.1 General	S				
8.2 Monitoring and measurement			1		
8.3 Control of NC product	S				
8.4 Analysis of data	S				
8.5 Improvement	S		1		
Assessed Organization: NASA, Marshall Space Flight Ctr.			4		Assessing Company: N Q A, USA
Rep's name: Robin N. Henderson	**Results**				Lead Assessor Name: Richard Giguere
Signature: Robin N. Henderson					Signature: Richard Giguere

* For each element, cross results of assessment: "S" for Satisfactory, "Ma" for major corrective action, "mi" for minor or "N/A" for non applicable

ASSESSMENT SCORING

(Member logo)

Organization : NASA, Marshall Space Flight Ctr.

	SCORING CHART	Result					
		Major CAR or minor CAR on Key requirement		Minor CAR on **non** Key requirement		NO CAR	RESULT
		Multiple findings	Single finding	Multiple findings	Single finding		
4	**Quality management system**					(100)	100
4.1	General requirements	0	10	25	40	50	50
4.2 & 4.3	Documentation requirements & Configuration management	0	10	25	40	50	50
5	**Management responsibility**					(150)	150
5.1	Management commitment	0	5	15	20	30	30
5.2	Customer focus						
5.3	Quality policy						
5.4	Planning	0	10	20	30	40	40
5.5	Responsibility, authority and communication	0	5	15	20	30	30
5.6	Management review	0	10	25	40	50	50
6	**Resource Management**					(100)	100
6.1	Provision of resources	0	10	25	40	50	50
6.2	Human resources						
6.3	Infrastructure	0	10	25	40	50	50
6.4	Work environment						
7	**Product realization**					(450)	
7.1	Planning of product realization	0	5	15	20	30	30
7.2	Customer related processes	0	10	30	50	60	60
7.3	Design and development						
7.3.1	*D& D Planning*	0	5	15	20	30	30
7.3.2-3-4	*Inputs, outputs & review*	0	5	15	20	30	5
7.3.5-6	*D&D verification & validation*	0	5	15	20	30	30
7.3.7	*Control of design and development changes*	0	5	15	20	30	30
7.4	Purchasing	0	10	30	50	60	10
7.5	Product and service provision						
7.5.1	*Control of production and service provision*	0	10	25	40	50	50
7.5.2	*Validation of processes for production and service provision*	0	10	20	30	40	40
7.5.3	*Identification and traceability*	0	10	20	30	40	40
7.5.4-5	*Customer property & preservation of product*	0	5	15	20	30	30
7.6	Control of monitoring and measuring device	0	5	10	15	20	20
8	**Measurement analysis and improvement**					(200)	200
8.1	General	0	5	10	15	20	20
8.2	Monitoring and measurement						
8.2.1	*Customer satisfaction*	0	5	10	15	20	20
8.2.2	*Internal audit*	0	5	15	20	30	30
8.2.3	*Monitoring and measurement of processes*	0	5	15	20	30	20
8.2.4	*Monitoring and measurement of product*	0	5	15	20	30	30
8.3	Control of nonconforming product	0	5	15	20	30	30
8.4	Analysis of Data	0	5	10	15	20	20
8.5	Improvement	0	5	10	15	20	15
					TOTAL	880 (1) or 1000	900
					SCORE	90/ 100	

The assessed Organization agrees on the Quality System scoring and Corrective Action requests		
Organization Representative : Robin N. Henderson	Signature :	Date : 11/17/06

(1) When 7.3 is not assessed : SCORE = $\frac{\text{RESULT X 100}}{880}$

APPENDIX A
AS9101

* * *

QUALITY SYSTEM QUESTIONNAIRE

Summary

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
4.2.4 QUALITY MANAGEMENT SYSTEM					
4.1 General requirements					
01 Has the organization established, documented, implemented and maintained a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard ?					
02 Does the organization : a) identify the processes needed for the quality management system and their application throughout the organization (1) ? b) determine the sequence and interaction of these processes (1) ? c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective ? d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes ? e) monitor, measure and analyze these processes ? and f) implement actions necessary to achieve planned results and continual improvement of these processes ?					
03 Are these processes managed by the organization in accordance with the requirements of this International Standard ?					
04 Where an organization chooses to outsource any process that affects product conformity with requirements, does the organization ensure control over such processes ?	P				
05 Is the control of such outsource processes identified within the quality management system ?					

Note : Processes needed for the quality management system referred to above should include processes for management, provision, product realization and measurement.

Guidance Note

1) Main process formally identified e.g. : list, flow diagram, etc.

Objective evidence assessed / Observations / Comments / N/A explanation

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
4.2. 4.2Documentation requirements					
4.2.1 General					
06 Does the quality management system documentation include : a) documented statements of a quality policy and quality objectives ? b) a quality manual ? c) documented procedures required by this International Standard ? d) documents needed by the organization to ensure the effective planning, operation and control of its processes ? e) records required by this International Standard (see 4.2.4) ? and ***f) quality system requirements imposed by the applicable Regulatory Authorities ?***		✓			
07 Does the organization ensure that personnel have access to quality management system documentation and are aware of relevant procedures ?		✓			
08 Do Customer and/or regulatory authority representatives have access to quality management system documentation ?		✓			
4.2.2 Quality manual MPD-1280.1 Rev Q					
09 Has the organization established and maintained a quality manual that includes (1) : a) the scope of the quality management system, including details of, and justification for, any exclusions ? b) the documented procedures established for the quality management system, or reference to them, and ***when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown (2) ?*** c) a description of the interaction between the processes of the quality management system ?		✓			

Note 1 : Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.
Note 2 : The extent of the quality management system documentation can differ from one organization to another due to
a) the size of organization and type of activities,
b) the complexity of processes and their interactions, and
c) the competence of personnel

Guidance Notes
1) Quality manual reference and issue
2) Check the procedure list

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed Manual for currency and continued compliance to AS9100.
Verified scope & description of interaction.
Verified access to QMS documentation by personnel and customer.
Evaluated documented system.

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*N/A: Not applicable - **N/E**: Not evaluated - **P**: Product - **M**: Management*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
4.2 Documentation requirements (continued)					
4.2.3 Control of documents					
10 Are the documents required by the quality management system controlled ?	M	✓			
11 Are records controlled according to the requirements given in 4.2.4 ?		✓			
12 Has a documented procedure been established to define the controls needed to : a) approve documents for adequacy prior to issue ? b) review and update as necessary and re-approve documents ? c) ensure that changes and the current revision status of documents are identified ? d) ensure that relevant versions of applicable documents are available at points of use ? e) ensure that documents remain legible and readily identifiable ? f) ensure that documents of external origin are identified and their distribution controlled ? and g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose ?		✓			
13 Does the organization coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements ?		✓			
4.2.4 Control of records					
14 Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system ?		✓			
15 Do records remain legible, readily identifiable and retrievable (1) ?		✓			
16 Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records ?		✓			
17 Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers ?		✓			
18 Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements ?		✓			
4.3 Configuration management					
19 Has the organization established, documented and maintained a configuration management process appropriate to the product ?	P				✓

Guidance Note

1) List records reviewed

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed Work Instructions for adequacy, use of current documents, availability, control of obsolete documents + suitable identification. - Sampled documents throughout audited areas as noted in checklist. Sampled records pertaining to Contracts, Space Act Agreements, Procurements Receiving Inspection, Design + Development, Internal Audit and Management Review for legibility, access, retrievability, storage, protection + disposition.

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N/A: Not applicable - **N/E**: Not evaluated - **P**: Product - **M**: Management

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
5 MANAGEMENT RESPONSIBILITY					
5.1 Management commitment					
01 Has Top management provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by (1) : a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements ? b) establishing the quality policy ? c) ensuring that quality objectives are established ? d) conducting management reviews ? And e) ensuring the availability of resources ?	M				✓
5.2 Customer focus					
02 Has Top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1) ? (See 7.2)		✓			
5.3 Quality policy					
03 Has Top management ensured that the quality policy : a) is appropriate to the purpose of the organization ? b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system ? c) provides a framework for establishing and reviewing quality objectives ? d) is communicated and understood within the organization (2) ? and e) is reviewed for continuing suitability ?		✓			
5.4 Planning					
5.4.1 Quality objectives					
04 Has Top management ensured that quality objectives, including those needed to meet requirements for product [see 7.1 a)] are established at relevant functions and levels within the organization (3) ?		✓			
05 Are the quality objectives measurable and consistent with the quality policy ?	M	✓			
5.4.2 Quality management system planning					
06 Has Top management ensured that : a) the planning of the quality management system is carried out in order to meet the requirements ~~given in~~(see 4.1), as well as the quality objectives ? and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented ?					✓

Guidance Notes

1) Evidence of management commitment
2) Identify and records method of communication
3) Review objectives and status of their implementation

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed + discussed customer interface and satisfaction measures for LOCAD contract and HERO project and in discussions with Business Development. Reviewed + Discussed policy + objectives for continued suitability and awareness.

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N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority					
07 Has Top management ensured that the responsibilities and authorities are defined and communicated within the organization (1) ?					/
5.5.2 Management representative					
08 Has Top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes : a) ensuring that processes needed for the quality management system are established, implemented and maintained ? b) reporting to top management on the performance of the quality management system and any need for improvement ? c) ensuring the promotion of awareness of customer requirements throughout the organization ? and ***d) the organizational freedom to resolve matters pertaining to quality ?***	M				/
5.5.3 Internal communication					
09 Has Top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system ?					/

Guidance Note

1) Identify and records method of communication within the organization

Objective evidence assessed / Observations / Comments / N/A explanation

*S: Satisfactory - **CAR**: Corrective action required – **Ma**: Major corrective action – **mi**: Minor corrective action*
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
5.6 Management review					
5.6.1 General					
10 Has Top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness (1) ?		✓			
11 Does this review include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives ?		✓			
12 Are records from management reviews maintained (see 4.2.4) ?		✓			
5.6.2 Review input Ref MPR1290:1 Rev H MPD 1000.1					
13 Does the input to management review include information on (2) : a) results of audits? b) customer feedback? c) process performance and product conformity? d) status of preventive and corrective actions? e) follow-up actions from previous management reviews? f) changes that could affect the quality management system? And g) recommendations for improvement?	M	✓			
5.6.3 Review output					
14 Does the output from the management review include any decisions and actions related to (2) : d) improvement of the effectiveness of the quality management system and its processes? e) improvement of product related to customer requirements? And f) resource needs?	M	✓			

Guidance Notes

1) Records management review frequency and functions involved (e.g : quality, production, etc.)
2) Verify the availability of input / output data such as: statistical data; graphics; summary tables; reports; etc.

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed activity related to CMC (Purc) and IMSB, Integrated Mgmt System Board
Interviewed personnel in the Business planning + Integration Office (CS10)

Observed Monthly meeting records relating to
- FY 06 Scorecard Metrics related to Goals/Objectives
- Action items + follow up from previous
- Audit results, CA/PA Status, Cust feedback, improvement recommendation + changes that could affect sys.
- Executive Summary, Meeting Minutes

Reference Charters: MPD 1150.1 Charter #'s MC-05-C, MC-25-A, MC-21-B

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
6. RESOURCE MANAGEMENT					
6.1 Provision of resources					
01 Has the organization determined and provided the resources needed: a) to implement and maintain the quality management system and continually improve its effectiveness ? And b) to enhance customer satisfaction by meeting customer requirements ?		✓			
6.2 Human resources					
6.2.1 General					
02 Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience (1) ?		✓			
6.2.2 Competence, awareness and training PS-OWI-02 Rev F Trng (PS10)					
03 Does the organization : a) determine the necessary competence for personnel performing work affecting product quality (2) ? per OFPP Policy Letter b) provide training or take other actions to satisfy these needs ? Hyhs / Trng. c) Evaluate the effectiveness of the actions taken ? Tests taken and eval. of perf. d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives ? e) maintain appropriate records of education, training, skills and experience (see 4.2.4) (3) ?	P	✓	on annual basis self assessments		
6.3 Infrastructure					
04 Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements ? Infrastructure includes, as applicable : a) buildings, workspace and associated utilities ? b) process equipment (both hardware and software) ? And c) supporting services (such as transport or communication) ?					✓
6.4 Work environment					
05 Does the organization determine and manage the work environment needed to achieve conformity to product requirements ?	P				✓

Note : Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

Guidance Notes Typ of Trng. – Blanket P.O. Process, Contract Changes, export Control

1) Review training Records and Plan (status of the current year and of the previous year)
2) Give examples of methods used to determine competence (e.g.: competence matrix, multiskill, ...)
3) Review training certificates for the certified personnel and training records (internal and external training courses)

Objective evidence assessed / Observations / Comments / N/A explanation

Procurement Training - Theresa Foley Butts / T. Jerry Williams

Certification of procurement personnel - per OFPP Policy Letter 05-01 - Developing + Managing acquisition workforce

Level I, II, III Certifications Level 1, 2, 3 Courses -

NASA Development Profile - Cert Level -

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7. PRODUCT REALIZATION					
7.1 Planning of product realization					
01 Does the organization plan and develop the processes needed for product realization ? (see 4.1)		✓			
02 Is planning of product realization consistent with the requirements of the other processes of the quality management system (see 4.1) ?		✓			
03 In planning product realization, does the organization determine the following, as appropriate : a) quality objectives and requirements for the product ? b) the need to establish processes, documents, and provide resources specific to the product ? c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance ? d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) ? e) ***the identification of resources to support operation and maintenance of the product ?***	P	✓			
04 Is the output of this planning in a form suitable for the organization's method of operations?		✓			

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed + discussed planning activities for LOCAD contract, High Energy Replicated Optics Project (HERO) including development of project plans, establishment + approval of required documents, development + maintenance of verification, monitoring, insp + test activities, maintenance of records and identification of appropriate resources to support operation

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

05 Does the organization determine : a) requirements specified by the customer, including the requirements for delivery and post-delivery activities ? HERO Project b) requirements not stated by the customer but necessary for specified or intended use, where known ? c) statutory and regulatory requirements related to the product ? and d) any additional requirements determined by the organization ?	M	✓			

7.2.2 Review of requirements related to the product MPR-1050.2 Rev A

06 Does the organization review the requirements related to the product ?		✓			
07 Is the review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that (1) : a) product requirements are defined ? b) contract or order requirements differing from those previously expressed are resolved ? c) the organization has the ability to meet the defined requirements ? ***And*** d) ***risks (e.g., new technology, short delivery time scale) have been evaluated ?*** NPR 1050.2	P	✓			
08 Are records of the results of the review and actions arising from the review maintained (see 4.2.4) (2) ?		✓	QRS		
09 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance ? MPD 1200.3 Rev H		✓			
10 Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements ? Amendment	P	✓			

Note : In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover the relevant product information such as catalogues or advertising material.

7.2.3 Customer communication

11 Does the organization determine and implement effective arrangements for communicating with customers in relation to : a) product information ? Cust Sat briefing - b) enquiries, contracts or order handling, including amendments ? and c) customer feedback, including customer complaints ?		✓			

Guidance Notes

1) Check that all affected functions are involved in the review
2) Give examples

+++ SAAM system

Objective evidence assessed / Observations / Comments / N/A explanation

Space Act Agreements interviewed TPOC -

SAAM #1370 (SAA8-061370)
Non Re-imbursable - w/ Internet Tech
Articles 24 - signed by both parties
Attachment - Cost estimate Summary

SAAM #732 -

SAAM #1243 - (SAA8-061243)
Agreement w/ AMSAT Academy -

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.3 Design and development					
7.3.1 Design and development planning					
12 Does the organization plan and control the design and development of product ?		✓			
13 During the design and development planning, does the organization determine : a) the design and development stages (1) ? - ***in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,*** b) the review, verification and validation that are appropriate to each design and development stage ? and c) the responsibilities and authorities for design and development ? HERO Project	M #3446	✓			
14 Where appropriate, due to complexity, does the organization give consideration to the following activities : LOCAD Project Plan - ***structuring the design effort into significant elements ?*** - ***for each element, analyzing the tasks and the necessary resources for its design and development. Does This analysis consider an identified responsible person, design content, input data, planning constraints, and performance conditions. Is the input data specific to each element reviewed to ensure consistency with requirements ?***		✓			
15 Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility ?		✓			
16 Is planning output updated, as appropriate, as the design and development progresses ?		✓			
17 Are the different design and development tasks to be carried out defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements (2) ? defined in Proj. Plan	P	✓			
7.3.2 Design and development inputs					
18 Are inputs relating to product requirements determined and are records maintained (see 4.2.4) (3) ? Do these inputs include : HERO - Reqts Doc. a) functional and performance requirements ? b) applicable statutory and regulatory requirements ? c) where applicable, information derived from previous similar designs ? and d) other requirements essential for design and development ?	M	✓			
19 Are these inputs reviewed for adequacy ?		✓			
20 Are requirements completed, unambiguous and not in conflict with each other ?		✓			

Guidance Notes

1) Give at least an example of a completed design & development plan, or an example of one in progress, that identifies the planning of tasks and key events.
2) Give an example
3) Review applicable input data (give examples)

Objective evidence assessed / Observations / Comments / N/A explanation

LOCAD Plan
Project Plan - Apr. 2005 - MSFC-PLAN-3446 (LOCAD)
System Reqts Doc. - MSFC-RQMT-3454 Rev C. define design inputs
Doc. Approved - Project Plan development + approval
Reviewed PDR, CDR + processing of RIDS, Acceptance Test

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.3 Design and development (continued)

7.3.3 Design and development outputs — MPR-7120.1

21 Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release ?		✓			
22 Do the design and development outputs : a) meet the input requirements for design and development ? b) provide appropriate information for purchasing, production and for service provision ? c) contain or reference product acceptance criteria ? d) specify the characteristics of the product that are essential for its safe and proper use ? ***and*** ***e) identify key characteristics, when applicable, in accordance with design or contract requirements ?*** LOCAD - acq sensitive materials - controls established	M	✓			
23 Is all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained defined by the organization; for example: - ***drawings, part lists, specifications ?*** HERI Project - ***a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product ?*** - ***information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product ?***	M		NC		

7.3.4 Design and development review

24 At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements (see 7.3.1) to (1) : (LOCAD) CDR Plan – 9 March 05 a) evaluate the ability of the results of Design and development to meet requirements ? b) identify any problems and propose necessary actions ? ***and*** all RIDS closed ✓ ***c) authorize progression to the next stage ?*** LOCAD RIDS - CDR-024, CDR-014	M	✓			
25 Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed ?		✓			
26 Are records of the results of the reviews and any necessary actions maintained (see 4.2.4) ?		✓			

7.3.5 Design and development verification

27 Is verification performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements ?		✓			
28 Are records of the results of the reviews and any necessary actions maintained (see 4.2.4) ?		✓			

Note : Design and/or development verification may include activities such as :
- **performing alternative calculations**
- **comparing the new design with a similar proven design, if available**
- **undertaking tests and demonstrations, and**
- **reviewing the design stage documents before release.**

5 Disposition on RIDS #014, 024

MPR-8060.3 Reqt's + Design Rev MSFC Pgm+Proj. Baseline

Guidance Notes

1) Give evidence of reviews

Objective evidence assessed / Observations / Comments / N/A explanation

RVc - Reqt's Verification + Compliance - MSFC-RQMT-3453 Rev B April '01
Maps interface reqts to parent reqt.
LOCAD PTS - Ref Reqt's Applicability Matrix
Sample 3.11.5.1, 3.12.6 Transportability

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.3 Design and development (continued)

7.3.6 Design and development validation

29 Is design and development validation performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known ?	P	✓			
30 Wherever practicable, is validation completed prior to the delivery or implementation of the Product ?		✓			
31 Are records of the results of validation and any necessary actions maintained (see 4.2.4) ?		✓			

Note:
-Design and/or development validation follows successful design and/or development verification.
-Validation is normally performed under operating conditions.
-Validation is normally performed on the final product, but may be necessary in the earlier stages prior to product completion.
-Multiple validations may be performed if there are different intended uses.

7.3.6.1 Documentation of design and/or development verification and validation

32 At the completion of design and/or development, does the organization ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions?	M	✓			

7.3.6.2 Design and/or development verification and validation testing

33 Where tests are necessary for verification and validation, are these tests planned, controlled, reviewed, and documented to ensure and prove the following (1) : *a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria ?* *b) test procedures describe the method of operation, the performance of the test, and the recording of the results ?* *c) the correct configuration standard of the product is submitted for the test ?* *d) the requirements of the test plan and the test procedures are observed ?* *e) the acceptance criteria are met ?*	P	✓			

Guidance Note

1) Give an example of a qualification report

Objective evidence assessed / Observations / Comments / N/A explanation

Verification (LOCAD) Test Report - Flight Syst. Int. + Test Branch # TROC-LOCAD-001
TPS # E152-LOCAD-FLT-028
Hardware Cof C - QR.6950 RUC # 3.10.4
Acceptance Review - Pre Shipment/Certification Rev Apr.'06
Review Board Cert.

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.3 Design and development (continued)

7.3.7 Control of design and development changes					
34 Are design and development changes identified and records maintained ?		✓			
35 Are the changes reviewed, verified and validated, as appropriate, and approved before implementation (1) ?	P	✓			
36 Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered ?	P	✓			
37 Does the organization's change control process provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement ?		✓			
38 Records of the results of the review of changes and any necessary actions maintained (see 4.2.4) ?		✓			

Guidance Note

1) Give an example

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed + Discussed design change process. - LOCAD & HERS project.
associated records -
Verification + Validation of changes
effects constituent parts

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.4 Purchasing					
7.4.1 Purchasing process MWI 5330.1					
39 Does the organization ensure that purchased product conforms to specified purchase Requirements ?	P	✓			
40 Is the type and extent of control applied to the Supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product ?		✓			
41 Is the organization responsible for the quality of all products purchased from suppliers, including customer-designated sources ?		✓			
42 Does the organization evaluate and select Suppliers based on their ability to supply product in accordance with the organization's requirements ? Award Fee Evaluation		✓			
43 Are criteria for selection, evaluation and re-evaluation established ?		✓			
44 Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4) ?		✓			
45 Does the organization :	M				
a) Maintain a register of approved Suppliers that includes the scope of the approval (1) ? ✓ Award fee eval - OK					
b) Periodically review Suppliers performance and use the records of these reviews as a basis for establishing the level of controls to be implemented (2) ? ✓ MWI 5330.1 Approved eval in Trends			NC		
c) Define the necessary actions to take when dealing with Suppliers that do not meet requirements ?					
d) Ensure where required that both the organization and all Suppliers use customer-approved special process sources ?					
e) Ensure that the function having responsibility for approving Supplier quality systems has the authority to disapprove the use of sources ?					

Guidance Notes

1) Review current list of approved Suppliers
2) Review suppliers performance / measurement system (e.g.: supplier rating, etc.)

Objective evidence assessed / Observations / Comments / N/A explanation

UNITES ~~SATE~~ Contract - Acquisition Planning — Reviewed per MPR5000.1

Patterson Machine -

1) Acquisition Planning Documentation
2) Solicitation Document
3) Copies of all offers Rec'd.
4) Source Selection Statement
5) Award Document
6) Contract Award Fee files

UNITES Contract - Interviewed Contracting officer - J. Jaehen
Performance Reqts Summary — Award fee Feb '06
Subjective Rating
Objective Rating - Contract Specific July - Sept

Supplier evaluation — Approved Suppliers
IMS
MWI 5330.1 par 6.4.2 Trend Anal. — Flexial
Annual eval of supplies. — Hamilton Sundstrand
Timken Super Precision

Cannot get to evidence

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.4 Purchasing (continued)					
7.4.2 Purchasing information					
46 *Does purchasing information describe the product to be purchased, inciuding where appropriate (1) :*	P				
a) *requirements for approval of product, procedures, processes and equipment ?*					
b) *requirements for qualification of personnel ?* QD-QE-001 Rev H		✓			
c) *quality management system requirements ?*					
d) ***the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data ?***					
e) ***requirements for design, test, examination, inspection and related instructions for acceptance by the Organization ?***					
f) ***requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing ?***					
g) ***requirements relative to :***					
- ***supplier notification to Organizationr of nonconforming product ? and***					
- ***arrangements for Organizationr approval of supplier nonconforming material ?***					
h) ***requirements for the supplier to notify the Organization of changes in product and/or process definition and, where required, obtain organization approval ?***					
i) ***right of access by the organization, their customer, and authorities to all facilities involved in the order and to all applicable records ? and***					
j) ***requirements for the supplier to flow down to subtier suppliers the applicable requirements in the purchasing documents, including key characteristics where required ?***					
47 Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier ?		✓			

Guidance Note

1) Examine purchase orders that apply to several types of procurement.

Objective evidence assessed / Observations / Comments / N/A explanation

Non-Competitive Acquisition – PS-OWI-07 Rev H
1st stage Review + Approval
Review + Execution of Procurement Doc. - PS-OWI-05 Rev L
QD-QE-001 - Rev H
① Request ID # CMJECS017R - Flight Hardware System Adding of Quality Codes - flow down req'ts
② Procurement for Wastewater Storage Tank Assy - (WSTA)
Flowdown of Req'ts - Contractor: FLEXIAL ASSUR ? / 90
include Rights Spec. flowdown to Sub Contr

JOFOC Justification for other than Full + Open Competition – Concurrence per PS-OWI-05
Synopsis development + response to synopsis – evaluation of response

Kelly Craig
Tanya
ECL 55

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.4 Purchasing (continued)					
7.4.3 Verification of purchased product MWI-5330.1 Rev G					
48 Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, they may include ***obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control, inspection and audit at supplier's premises, review of the required documentation, inspection of products upon receipt, and, delegation of verification to the supplier, or supplier certification ?***	P	✓			
49 Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure ? Waiver sub. + appr.		✓			
50 Where the organization utilizes test reports to verify purchased product, is the data in those reports acceptable per applicable specifications (1) ?		S			
51 Does the organization periodically validate test reports for raw material (1) ? IAR# 5330, 5334/5					
52 Where the organization delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained (1) ? NONE		✓			
53 Where the organization or its customer intends to perform verification at the supplier's premises, does the organization state the intended verification arrangements and method of product release in the purchasing information?		✓			
54 Where specified in the contract, is the customer or the customer's representative afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements ? Flow down to Areas		✓			
55 It is ensured that verification by the customer is not used by the organization as evidence of effective control of quality by the supplier (it does not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer) ?		✓			

Guidance Note

1) Give an example

Objective evidence assessed / Observations / Comments / N/A explanation

① IAR# 5330
Validation of Test Reports – Sample # 9622011 - Validation
Cores supplied Material

② Incoming Insp. # 05376 - Insp Rept's Ham. Sundstrand

ECLSS ③ #05376 – Timpken Super Precision – AS9100? Stamped acceptance ✓
NSFC Form 312 OK

④ P/N 96M22009 N/R IAR# 5335 – IMS, Inc.
Rejected – Waiver Submitted + accepted - IMS-001
Order# NNM06AD68P - calls out ISO9001:

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision					
7.5.1 Control of production and service provision					
56 Does planning consider, as applicable : - *the establishment of process controls and development of control plans where key characteristics have been identified* - *the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization* - *the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and* - *special processes (see 7.5.2).*	P				/
57 Does the organization plan and carry out production and service provision under controlled conditions (1). Do these controlled conditions include, as applicable : a) the availability of information that describes the characteristics of the product ? b) the availability of work instructions, as necessary ? c) the use of suitable equipment ? d) the availability and use of monitoring and measuring devices ? e) the implementation of monitoring and measurement ? f) the implementation of release, delivery and post-delivery activities ? *g) accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product) ?* *h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized ?* *i) provision for the prevention, detection, and removal of foreign objects ?* *j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality ? and* *k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations) ?*	P P				/

Guidance Notes

1) List the Part Number(s) used for this review

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.1.1 Production documentation					
58 Are production operations carried out in accordance with approved data ?					✓
59 Does the data contain as necessary : *a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1) ? and* *b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use ?*	P				✓
7.5.1.2 Control of production process changes					
60 Are persons authorized to approve changes to production processes identified (1) ?	M				✓
61 Has the organization identified and obtained acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements ?					✓
62 Are changes affecting processes, production equipment, tools and programs documented ?	P				✓
63 Are procedures available to control their implementation ?					✓
64 Are the results of changes to production processes assessed to confirm that the desired effect has been achieved without adverse effects to product quality ?	P				✓
7.5.1.3 Control of production equipment, tools and numerical control (N.C.) machine programs					
65 Are production equipment, tools and programs validated prior to use and maintained and inspected periodically according to documented procedures ?	P				✓
66 Does validation prior to production use include verification of the first article produced to the design data/specification ?	P				✓
67 Are storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage ?					✓
7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities					
68 When planning to temporarily transfer work to a location outside the organization's facilities, does the organization define the process to control and validate the quality of the work ?	M				✓

Guidance Notes

1) Clearly defined list or procedures

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.1.5 Control of service operations					
69 Where servicing is a specified requirement, do service operation processes provide for : *a) a method of collecting and analyzing in-service data ?* *b) actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements (1) (2) ?* *c) the control and updating of technical documentation ?* *d) the approval, control, and use of repair schemes (3) ? and,* *e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities) ?*					
7.5.2 Validation of processes for production and service provision					
70 Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered) (4) ? Note :These processes are frequently referred to as special processes.	P				
71 Does validation demonstrate the ability of these processes to achieve planned results ?					
72 Has the organization established arrangements for these processes including, as applicable : a) defined criteria for review and approval of the processes ? *-qualification and approval of special processes prior to use ?* b) approval of equipment and qualification of personnel ? c) use of specific methods and procedures ? *- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto (5) ?* d) requirements for records (see 4.2.4) ? e) and ~~Re-evaluation~~revalidation ?	M				

Guidance Notes

1) Review reports issued following visits to the customer (technical support). Comment on method of collection of in service data. Examine some investigation reports
2) Review evidence of implementation of corrective and preventive actions.
3) Review evidence of what has been assessed (e.g.: maintenance manual, repair manual, information to customer)
4) Verify the existence of list of special processes.
5) Give examples

Objective evidence assessed / Observations / Comments / N/A explanation

S: Satisfactory - CAR: Corrective action required – Ma: Major corrective action – mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.3 Identification and traceability					
73 Where appropriate, has the organization identified the product by suitable means throughout product realization ?					
74 Does the organization maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration ?	P				
75 Has the organization identified the product status with respect to monitoring and measurement requirements ?					
76 When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organization establish and document controls for the media (1) ?					
77 Where traceability is a requirement, does the organization control and record the unique identification of the product (see 4.2.4) ?					
78 According to the level of traceability required by contract, regulatory, or other established requirement, does the organization's system provide for (2) : ***a) identification to be maintained throughout the product life ?*** ***b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch ?*** ***c) in any assembly, the identity of its components and those of the next higher assembly to be traced?*** ***d) in any given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved ?***	P				

Note: In some industry sectors, configuration management is a means by which identification and traceability is maintained.

7.5.4 Customer property					
79 Does the organization exercise care with customer property while it is under the organization's control or being used by the organization (3) ?					
80 Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product ?					
81 Does the organization define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer ?					

Note: Customer property can include intellectual property, ***including customer furnished data used for design, production and/or inspection.***

Guidance Notes

1) Give examples of method(s) used
2) Give examples of traceability level applied (up and down)
3) Identify types of product supplied by the customer.

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.5 Preservation of product					
82 Does the organization preserve the conformity of product during internal processing and delivery to the intended destination ?					
83 Does the preservation include identification, handling, packaging, storage and protection ?					
84 Does preservation also apply to the constituent parts of a product ?					
85 Does preservation of product also include, where applicable in accordance with product specifications and/or regulations, provisions for : ***a) cleaning ?*** ***b) prevention, detection and removal of foreign objects ?*** ***c) special handling for sensitive products ?*** ***d) marking and labeling including safety warnings ?*** ***e) shelf life control and stock rotation ?*** ***f) special handling for hazardous materials ?***	P				
86 Does the organization ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration ?					

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.6 Control of monitoring and measuring devices					
87 Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1) (1) ?	P				
88 Does the organization maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria ? ***Note : Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.***	M				
89 Does the organization establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements ?					
90 Does the organization ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out ?					
91 Where necessary to ensure valid results, is measuring equipment : a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (2) ? b) adjusted or re-adjusted as necessary ? c) identified to enable the calibration status to be determined ? d) safeguarded from adjustments that would invalidate the measurement result ? e) protected from damage and deterioration during handling, maintenance and storage ? ***f) recalled to a defined method when requiring calibration ?***					
92 Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements ?					
93 Does the organization take appropriate action on the equipment and any product affected ?	P				
94 Are records of the results of calibration and verification maintained (see 4.2.4) ?					
95 When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed ?	P				
96 Is this undertaken prior to initial use and reconfirmed as necessary ?					

Guidance Notes

1) Review that the organization has a process for ensuring the capability of measurement system (e.g. Interval Analysis, Resolution Analysis, Gage Repeatable & Reproducibility, etc.)
2) Ensure the links to the recognized international / national standard.

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8 MEASUREMENT, ANALYSIS AND IMPROVEMENT					
8.1 General					
01 Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed (1) : a) to demonstrate conformity of the product ? b) to ensure conformity of the quality management system, and ? c) to continually improve the effectiveness of the quality management system ?	M				✓
02 Does this include determination of applicable methods, including statistical techniques, and the extent of their use ?					✓

***Note** : According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support :*

-design verification (e.g., reliability, maintainability, safety) ;

-process control :

- *selection and inspection of key characteristics;*
- *process capability measurements;*
- *statistical process control;*
- *design of experiment;*

-inspection – matching sampling rate to the criticality of the product and to the process capability ;

-failure mode and effect analysis.

Guidance Notes

1) Give examples of data

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.1 Customer satisfaction MPR-1280.8 Rev B-					
03 As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has met customer requirements (1) ? Interviewed Bus. Planning + Dev. Mgr.		✓			
04 Are the methods for obtaining and using this information determined? 2006 Cust Sat.		✓			
8.2.2 Internal audit MPR-1280.6					
05 Does the organization conduct internal audits at planned intervals to determine whether the quality management system (2) : a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization? and b) is effectively implemented and maintained?	M	✓			
06 Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?		✓			
07 is the audit criteria, scope, frequency and methods defined?		✓			
08 Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process (3) ?		✓			
09 Does the organization ensure internal auditors do not audit their own work ?		✓			
10 Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure ?		✓			
11 Do the management responsible for the areas being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes ?	M	✓			
12 Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2) (4) ?		✓			
13 Are detailed tools and techniques developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements ?		✓			
14 Are the selected internal audit tools acceptable in measuring the effectiveness of the internal audit and overall organization performance ?		✓			
15 Do internal audits also meet contract and/or regulatory requirements ?		✓			

Guidance Notes

1) Give examples of how customer's satisfaction is measured, committed, and acted upon.
2) Review of audit plan (status of the previous year and progress of the current year).
3) Check the list of approved auditors.
4) Review type of audits (questionnaire, synthesis, circulation, request for corrective actions, corrective actions follow-up).

Objective evidence assessed / Observations / Comments / N/A explanation

Audit schedule - 2006

Audit #ER07200601 - inbrief/outbrief - audit summary
7/31-8/14/06 NCR 887, 888, 889, 890
audit Report Trending + reporting of COI's

Audit AS05200601 - inbrief/outbrief - 5/15-22/06
Audit Report, Summary NCR 881, 882, 883, 884

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.3 Monitoring and measurement of processes					
16 Does the organization apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes ?					
17 Do these methods demonstrate the ability of the processes to achieve planned results ?					
18 When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product ?					
19 In the event of process nonconformity, does the organization (1) : ***a) take appropriate action to correct the nonconforming process ?*** ***b) evaluate whether the process nonconformity has resulted in product nonconformity ? and*** ***c) identify and control the nonconforming product in accordance with clause 8.3 ?***	P				
8.2.4 Monitoring and measurement of product					
20 Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met ?	P				
21 Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) ?					
22 When key characteristics have been identified, are they monitored and controlled ?	P				
23 When the organization uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use ?					
24 Does the plan preclude the acceptance of lots whose samples have known nonconformities ?					
25 When required, is the plan submitted for customer approval ?					
26 Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities ?	P				
27 Is evidence of conformity with the acceptance criteria maintained ?					
28 Do records indicate the person(s) authorizing release of product (see 4.2.4) ?					
29 Is product release and service delivery held until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer ?					

Guidance Note

1) Give examples of non conformity (product, process, ...).

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.4.1 Inspection documentation					
30 Are measurement requirements for product or service acceptance documented ?					
31 Does this documentation, which may be part of the production documentation, include : *a) Criteria for acceptance and/or rejection ?* *b) Where in the sequence measurement and testing operations are performed ?* *c) a record of the measurement results ? and* *d) type of measurement instruments required and any specific instructions associated with their use ?*	P				
32 Do test records show actual test results data when required by the specification or acceptance test plan ?					
33 When required to demonstrate product qualification does the organization ensure that records provide evidence that the product meets the defined requirements ?					✓
8.2.4.2 First article inspection					
34 Does the organization's system provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result (1) ?	P				✓

Guidance Note

1) Give examples of first article (new product and change).

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.3 Control of nonconforming product					
Note: **The term "nonconforming product" includes nonconforming product returned from a customer.**					
35 Does the organization ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery ?	P				
36 Are the controls and related responsibilities and authorities for dealing with nonconforming product defined in a documented procedure ?					
37 Does the organization's documented procedure define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions ?					
38 Does the organization deal with nonconforming product in one or more of the following ways by: a) taking action to eliminate the detected nonconformity ? b) authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer ? c) taking action to preclude its original intended use or application ?	P				
39 Does the organization prevent dispositions of use-as-is or repair, unless specifically authorized by the customer, if ***- the product is produced to customer design ? or*** ***- the nonconformity results in a departure from the contract requirements ?*** ***(Unless otherwise restricted in the contract, is organization-designed product, which is controlled via a customer specification, dispositioned by the organization as-use-as is or repair, provided the nonconformity does not result in a departure from customer-specified requirements ?)***					
40 Is product dispositioned for scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable ?	P				
41 Are records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, maintained (see 4.2.4) ?					
42 When nonconforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements ?					
43 When nonconforming product is detected after delivery or use has started, does the organization take action appropriate to the effects, or potential effects, of the nonconformity ?	P				
44 In addition to any contract or regulatory authority reporting requirements, does the organization's system provide for timely reporting of delivered nonconforming product that may affect reliability or safety ?	P				
45 Does notification include a clear description of the nonconformity, which includes as necessary, parts affected, customer and/or organization part numbers, quantity, and date(s) delivered ?					

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.4 Analysis of data					
46 Does the organization determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made ?	M	✓			
47 Does this include data generated as a result of monitoring and measurement and from other relevant sources ?		✓			
48 Does the analysis of data provide information relating to : a) customer satisfaction (see 8.2.1) (1) ? b) conformity to product requirements (see 7.2.1) ? c) characteristics and trends of processes and products including opportunities for preventive action ? And d) suppliers ?		✓			

Guidance Note

1) Give examples and check how the organization measures the effectiveness.

Objective evidence assessed / Observations / Comments / N/A explanation

Observed analysis of data via discussion and reporting at the management Council - related to customer Satisfaction performance against goal/objectives, process performance, Trends - and Supplier performance

Interviewed individuals from ESIO, Business Planning + Integration Office

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.5 Improvement					
8.5.1 Continual improvement					
49 Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review ? Lean initiatives - Mgt Rev.		✓			
8.5.2 Corrective action					
50 Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence (1) ?	P	✓			
51 Are Corrective actions appropriate to the effects of the nonconformities encountered ?		✓			
52 Is a documented procedure established to define requirements for :					
a) reviewing nonconformities (including customer complaints) ? RCAR 244					
b) determining the causes of nonconformities ? RCAR 243 - closed.					
c) evaluating the need for action to ensure that nonconformities do not recur ? RCAR #242 - closed.					
d) determining and implementing action needed ? QSDN # 177			NC		
e) recording of the results of the action taken (see 4.2.4) ? ↳ RCAR #246					
f) reviewing corrective action taken ? product to ship stop no response - request sent to 7/1/07					
g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause ? and					
h) specific actions where timely and/or effective corrective actions are not achieved ?					
8.5.3 Preventive action NPR 7120.6 Lessons Learned					
53 Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence (2) ?	M	✓			
54 Are preventive actions appropriate to the effects of the potential problems ?		✓			
55 Is a documented procedure established to define requirements for :					
a) determining potential nonconformities and their causes ?					
b) evaluating the need for action to prevent occurrence of nonconformities ?		✓			
c) determining and implementing action needed ? preventive action discussed @ Mgt Rev.					
d) recording of the results of the action taken (see 4.2.4) ? and					
e) reviewing preventive action taken ?					

Guidance Notes

1) Select a non-conforming part and use 52 a) through h) to check for effectiveness.
2) Select a non-conforming part and use 55 a) through e) to check for effectiveness.

Objective evidence assessed / Observations / Comments / N/A explanation

Customer Complaint - #403 → RCAR #245
↳ user (NASA) complaint
#401 → Customer feedback

DR-7570 1/25/06 P/N 96M11800-003A - No Disposition, status OPEN, No acc.
DR-7545 3/7/06 P/N 96M00066-003 - No Disp., status open, No acc
DR-7590 3/31/06 ——— Disp verification Parts TAG
DR-7585 3/21/06 waiver → RCAR #241 - CAUSE/CA

} No RCAR

Parts TAG

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Annex A
(informative)

Bibliography

ISO 9000: 2000	Quality management systems – Fundamentals and vocabulary
ISO 9001: 2000	Quality management systems – Requirements
ISO 10011	Guidelines for auditing quality systems
EN 9100 – Section 1	Aerospace series – Quality management systems – Requirements (based on ISO 9001: 2000)